Comments on CDRH July 30 draft Medical Glove Guidance Manual

A. Douglas, Health Canada, medicaldevices@ottawa.com, October 14, 1999

GENERAL COMMENT

Contact Names

An Appendix giving CDRH contact names and emails, and each contact's area of expertise pertaining to gloves, should be included the document

HTML Update page

A document of this scope will require frequent updates. A permanent "update" Gloves webpage should be established and the page (URL) given in the document; anyone having a paper copy of the Manual could refer to the update page to see if there have been changes. More than just posting the most recent version, the update page also would describe changes made since the older version.

Format

Adding Table of Content bookmarks to the PDF document will make navigation easier.

Organization

It is confusing that product specifications, such as maximum allowable levels of powder and protein, are apparently discussed under *labeling.* Product specifications should be given in Sections 3 - 5.

SECTION-BY-SECTION COMMENT

Introduction (1-1)

Handwashing guidelines[1] usually discuss the proper use of gloves. The glove guidance should set

[1] Examples: http://wonder.cdc.gov/wonder/prevguid/p0000191/p0000191.htm and http://www.hc-sc.gc.ca/hpb/lcdc/publicat/ccdr/98pdf/cdr24s8e.pdf

the use of gloves in context for greater infection control issues: there should be mention of the need for handwashing as an essential part of the effective use of gloves, either in Introduction (1-1) or Adequate Directions for Use (6-2).

Chemical Sensitivity (pg. 1-3)

Chemical sensitivity problems are not limited to natural rubber latex (NRL). The same chemicals used in synthetic rubbers can cause problems, and sensitivity to vinyl has also been reported.

There should be a statement on the safety of phthalate plasticizers as used in vinyl gloves: exposure levels, toxicity are "recent activities".

Radiographic Protection Gloves (pg. 3-8)

Is it true that these gloves are used to protect patients from radiation?

NonMedical (Embalming, Cleaning, Household) Gloves (pg. 3-8)

Give the FDA's definitive of a "medical" glove. Explain why these gloves do not fit the definition, are therefore not medical devices, and therefore not regulated, even though their failure can result in disease transmission.

Leak Detectors (pg. 3-9)
Table 3.2 lists leak detectors as Class II, but page 3-8 lists them as Class I. For keyword purposes these should also be described as "barrier integrity monitors".

Glove Lubricants (4-1)

List materials used until now on exam gloves which has been granted permission to market; this will give essentially a list of acceptable materials (lactose, oatstarch?). Discuss claims for "curative" powders (oatstarch) proposed for use on nonsterile exam gloves.

Discuss antimicrobial lubricants/coatings on gloves (Daltex - General Hospital and Personal Use Devices Panel - March 11, 1996), and regulatory requirements for product marketing.

Statement of Identity (6-2)

Gloves are often labeled only "nonlatex" or "synthetic". This guidance document should explain *why* "'Synthetic' used alone does not fully characterize the composition of the glove and may mislead the purchaser." For example, latex and hydrocarbon polymer gloves are susceptible to damage from mineral oil but not from rubbing alcohol, while a vinyl gloves are the opposite.

Quality System: Design Verification and Validation (10-16)

There should be verification that during use the device did indeed perform as required. In other words, there should be evidence that gloves maintain their most important characteristic - **barrier integrity** - throughout a period of normal use and doffing. There is considerable experimental evidence that, in fact, most gloves do not maintain barrier integrity during use[2]. Design validation (pg. 10-17) of barrier integrity is more important than any of the characteristics such as color or odor, and should be specifically mentioned as mandatory - to reinforce the mention in 6-12 wants "better barrier protection".

Quality System - Finished Glove evaluation s (pg 10-47 and 10-48)

"...there is some concern" is vague. A specific example (as is done in the Bioburden section) of the past experience FDA has had with offshore product that developed pinholes during storage should be given, stating elapses times from manufacture that may be sufficient to cause problems for some products. Guidance should state: it is not sufficient to manufacture gloves without holes: the product process must be validated with real-time aged product to ensure that the product is still a good barrier when delivered to the consumer. The Guidance could be in either Quality System or under Expiration Date (pg. 6-4)

Under this section of QS attention could be drawn to the need for proper storage of finished product to avoid spontaneous combustion (the infamous New York City burning gloves episode, 1995).

Quality system - Complaints (pg 10-54)

Add "Users are often unaware that their gloves have failed in use and will therefore not report the

[2] A. Rego, L. Roley. *Am. J. Infection Control*. October 1999 · Volume 27 · Number 5. http://www1.mosby.com/scripts/om.dll/serve?action=searchDB&searchDBfor=art&artType=full&id=a96790

device failure"[3]

Quality System - Medical Device Reporting (MDR) (10-55)

The Guidance document should give examples of what is, and what is not, reportable. For example, does the hazard have to be to a patient only, or is an adverse effect upon employee reportable?:
- anaphylactic reaction due to glove exposure?
- delayed type IV skin reaction?
- known glove barrier failure (recall the case of the Florida dentist transmitting AIDS)

Adequate Directions for Use (pg. 6-2)

change "if a symbol is used" to "*whether or not* a symbol is used". There should be a requirement that all exam gloves be labelled "for **single use** only" or similar wording, and that "disposable" is not similar wording. "Single use" implies that the glove is to be used for only one purpose or patient. "Disposable" implies that a glove may be re-used until it is worn out (as, for example, with a disposable flashlight), but this is contrary to safe medical practice. Multiple-use "disposable" gloves for re-sterilization are seldom, if ever, sold in developed countries.

Powder and Protein Labelling (pg. 6-3)

These are 2 separate issues and should be discussed separately. They could be interrelated only for latex gloves, because powder can spread latex allergen – but FDA has not proposed any different powder levels for latex gloves vs. nonlatex gloves, so they remain 2 separate issues. Powder relates to all gloves, protein only to NRL gloves.

Powder Labelling (pg. **6-3)**

The implication of the proposed powder level labelling is that FDA is willing to permit hazardous devices on the market, provided they are labeled as hazardous and exceeding FDA recommendations. The proposed labelling is therefore unacceptable.

The statement "FDA recommends that this product contain not more than 120 mg powder... per

[3] Kotilainen H, Brinker J, Avato J, et al. Latex and Vinyl Examination Gloves: Quality Control Procedures and Implications for the Health Care Workers. Arch. Intern. Med. 1989; 149: 2749-53 notes that for the vinyl gloves of which 28% were leakers, " the nurses did not recall any holes or other defects"

glove" should not be required, if it is only a recommendation. It implies that 120 is a magic number. If powder exceeding 120 mg is not recommended for health reasons, and in fact FDA is setting maximum permissible limits to protein and powder levels, those limits should be set out in Sections 4 and 5.

Powder on latex gloves is "associated with adverse reactions" at least as much as powder on synthetic gloves, so it is unfair to single out synthetic gloves with this "association" labeling.

There is little purpose in regulating a maximum amount of powder level, as this would likely be deemed unenforceable. By permitting the continued sale of powder gloves, FDA allows powder levels to vary 100-fold among glove brands, and accepts the presence of powder as permissible. How can a powder glove, having already 100 times the powder load of a clean glove, be considered a "hazard" just because it has 140 mg of powder rather than 120? In any case, no manufacturer places more powder than necessary on a glove. The FDA can expend its resources in a more useful fashion that measuring the amount of powder on a heavily powdered glove.

Powder is indeed "associated with adverse reactions", so the FDA should recommend, as has NIOSH, "that consumers[4] should minimize powder exposure by **choosing powderless gloves**". This recommendation should be made through publications and professional education, but could also be printed on every powder glove label.

Meanwhile, labeling should be short and simple. It should give a concise factual statement as to powder level and how it was measured. Therefore, the statement on powder levels should use the same wording for both powderless and powder gloves. "This product contains XX" is easier to understand than "This product contains no more than XX".

Protein Labeling (pg. 6-3)

The implication of the proposed protein level labelling is that FDA is willing to permit hazardous devices on the market, provided they are labeled as hazardous and exceeding FDA recommendations. The proposed labelling is therefore unacceptable.

The statement "FDA recommends that this product contain not more than... 1200 micrograms protein per glove" should not be required, if it is only a recommendation. It implies that 1200 is a magic number. If protein exceeding 1200 micrograms is not recommended for health reasons,

[4] NIOSH recommendation is only for latex powder in order to protect workers. Since patient wound exposure to any powder is undesirable, FDA can extend the recommendation to gloves of all types.

and in fact FDA is setting maximum permissible limits to protein levels, those limits should be set out in Sections 4 and 5.

Labeling should give a factual statement as to protein level; it should also state the method used to measure the level (methods may change in the coming years).

The caution statement "Safe use of these gloves..." is a matter of contention (some allergic individuals use clean latex gloves with no problems) and FDA should not require a label statement that may one day, in fact, be proven untrue. In any case the caution statement is unnecessary, as the product is already labeled as "may cause allergic reactions".

Measurement (pg.6-8) "...if the ongoing work on ASTM D 5712 " might better be phrased "ongoing work of Committee D11 on Rubber, Subcommittee D11.40", since a new test method might come out in a different standard.

Protein Labeling - Measurement of Protein Levels (pg. 6-4)

Protein levels are a characteristic of the NRL material. Characteristics are normally measured in per cent, or proportion. For example, the various chemicals in bottled water are measured in units/unit of water; seldom is absolute amount/bottle of water specified.
Protein levels therefore be measured using a proportion (ratio) measure.

Allergen/unit mass of gloves (microgram/gm) has often been used to report protein levels. However, it is misleading because a thick glove will show a lower protein level than a thin glove of the same size, even though both gloves have the same allergen/unit surface area.

The measurement of protein levels should be as clinically relevant as reasonably possible. The amount of patient (or worker) exposure of allergen/unit body mass is most clinically relevant. This would correlate best to allergen/unit surface area for a glove. While hand sizes vary, a person with a large hand (and therefore larger skin surface exposure and greater powder inhalation from donning) would typically have a larger body mass. Allergen/unit surface area, typically micrograms/sq.cm. should therefore be used.

Patient Examination Gloves: Section 8 (pg. 8-12)

This Section should be re-organized. Elongation and strength should be reported for all gloves, including vinyl. A breakout for nitrile, vinyl and latex should then be done, for attestation to ASTMD6319, 5250 or 3578 (not 3577) respectively.
Of course, 6319 can now be added throughout the Guidance document.

Compliance (pg. 11-9)

If ASTM leakage requirements for exam gloves must be met in order to receive a 510(k), then FDA, when testing to 21 CFR §800.20 is no longer testing to 510(k) requirements, because the ASTM standards have a tighter AQL for leakage. It should be clarified which gloves must to meet ASTM 2.5% AQL and which gloves need meet FDA 4% AQL. Clearly, for gloves claiming to meet ASTM 1999 standards, compliance testing should be done to those standards.

Voluntary Standards (12-1)

Hopefully this Section will soon need updating. It is likely that Canada will soon reference the ISO standards for patient and surgical gloves. The ISO11193 standard may soon change to include specifications for nitrile rubber gloves.

Butler, Jennie C
From: Dillard, Sharon F.
Sent: Tuesday, November 16, 1999 9:57 AM
To: Dockets, FDA
Cc: Olson, Jean M.; Stratmeyer, Melvin E.; Dillard, Sharon F.
Subject: FW: Glove Policy - FDA - Comment
Dear Dockets Manager,

These comments were forwarded from Canadian Medical Devices Agency Staff on the glove powder proposed rule and on the glove manual. Please include them with the other comments.

If you have any questions, or if for some reason the attached document does not transfer, I can be contacted at 301-594-3585.

Sharon Dillard

-----Original Message-----
From: A_Douglas@hc-sc.gc.ca [SMTP:A_Douglas@hc-sc.gc.ca]
<mailto:[SMTP:A_Douglas@hc-sc.gc.ca]>
Sent: Wednesday, October 20, 1999 3:50 PM
To: SFD@CDRH.FDA.GOV
Cc: Irwin_Hinberg@hc-sc.gc.ca; Barbara_Harrison@hc-sc.gc.ca
Subject: Glove Policy - FDA - Comment

Sharon
I have put together the comments, here, for consideration. I will mail snailmail copy as formally instructed in the draft Manual, but could you send this electronic copy to the CDRH "glove people" (you?) taking all comments? (Indeed, maybe it is time Gazette notices and Drafts asked that comments be emailed as well as snailmailed - it sure is a lot easier to work from electronic copy!)
Andrew